

## REMARKS

Claims 1, 4-10, 12 and 43-45, and 59-61 are pending in the instant application. Claims 13-42 and 46-58 were previously cancelled, and Claims 2-3 and 11 are cancelled herewith, all without prejudice or disclaimer. Claims 59-61 have been added. Claims 1, 4, 8, 10, 12, 43, and 45 have been amended without prejudice to their refiling as originally filed in future continuation applications. Support for the new claims, and for the amendments, may be found in the claims as originally filed and throughout the specification, for example on page 22, line 31 to page 23, line 2. No new matter has been added as a result of the above-described amendments. The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

### 1. Claim Rejections – 35 U.S.C. § 112, second paragraph

(A) The Office Action asserts that the Office maintains a rejection of Claims 1-3 under 35 U.S.C. § 112, second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office Action asserts that Applicant fails to particularly point out and distinctly claim the “LGR8” polypeptide by sufficient identifying characteristics. Applicants respectfully traverse the assertion.

Applicants first note that the term “LGR8” is not recited anywhere in any of Claims 1-3. The current Office Action, in discussing the rejection, refers to Claim 8, and the previous Office Action, in which the original rejection was issued, rejected Claim 8. Therefore Applicants presume that the reference to Claims 1-3 was inadvertent, and the rejection is of Claim 8, *not* of Claims 1-3, Applicants address the rejection herewith accordingly.

Applicants note that in view of the definition in the specification, it would be clear to one of ordinary skill in the art what the term “LGR8,” means as recited in Claim 8. However, solely in order to expedite prosecution of the instant application, Applicants have amended Claim 8 to refer to specifically claimed sequences, and contend that as amended, Claim 8 is definite. Additionally, for consistency, Applicants have similarly amended Claims 10 and 12.

Applicants, believing that the rejection of the pending claims based on 35 U.S.C. §112, second paragraph, for indefiniteness has been overcome by amendment or traversed by argument, respectfully request that this ground of rejection be withdrawn.

## **2. Claim Rejections – 35 U.S.C. § 101**

The Office Action maintains a rejection of Claims 1-12 and 43-45 under 35 U.S.C. § 101, asserting that the claimed invention lacks utility. Applicants respectfully traverse this rejection. Applicants note that with regard to Claims 2-3 and 11, the rejection is moot based on the cancellation of these claims.

In setting forth the rejection, the Office Action has stated that “the instant specification does not identify a physiological process such as blood pressure, heart rate, taste or sensation of pain which one could expect to influence by the administration of a compound that has been identified by employing a protein of the instant invention” (page 4 of Office Action). Applicants traverse, and note that the specification does in fact set identify a physiological processes mediated by proteins encoded by the claimed nucleic acids which one could expect to influence by administration of a compound that has been identified by employing a protein of the instant invention. In fact, the specification sets forth more than one such physiological processes: cachexia and muscular dystrophy (page 84, lines 18-19); miscarriage, endometriosis, uterine cancer, and female infertility (page 84, lines 24-25); Cushing’s disease and Addison’s disease (page 84, line 30 to page 85, line 1); leukemia (page 85, line 12); anemia, hypertension, and low blood pressure (page 85, lines 18-19); female infertility and ovarian cancer (page 85, lines 24-25); etc. Use of the proteins encoded by the claimed nucleic acid molecules to identify agonists or antagonists to these proteins is of specific, substantial, and credible utility in treating, preventing, or mediating these recited disorders.

Applicants respectfully submit that because the instant application contains an assertion of a specific and substantial utility for the claimed invention that would be credible to one of skill in the art, the rejection under 35 U.S.C. § 101 should be withdrawn.

## **3. Claim Rejections – 35 U.S.C. § 112, first paragraph**

The Office Action maintains a rejection of Claims 1-12 and 43-45 under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the Office Action mailed February 25, 2004, and according to paragraph 8 of the instant Office Action.

(A) Applicants note that the instant Office Action provides two paragraphs labeled “9,” and presume the above reference to paragraph 8 in the instant Office Action is in fact a reference to the first paragraph labeled “9,” which lays forth the utility rejection. In connection with this it is the

Applicants understanding that the Office Action has maintained the rejection of the pending claims under 35 U.S.C. § 112, first paragraph under the assertion that because the claimed invention is not supported by a specific and substantial asserted utility or a well-established utility, one skilled in the art would not know how to use the claimed invention.

Applicants contend that this ground of rejection stands or falls with the rejection asserted in the Office Action under 35 U.S.C. § 101. As set forth above, Applicants have provided affirmative evidence that the asserted utility would be credible to one of ordinary skill in the art. Applicants respectfully contend that because the instant application in fact contains an assertion of a specific and substantial utility for the claimed invention that one of ordinary skill in the art would find to be credible, this rejection under 35 U.S.C. § 112, first paragraph, is overcome, and should be withdrawn.

**(B)** The Office Action maintains a rejection of Claims 1-3 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action asserts that the Applicant has not provided evidence to demonstrate that the skill artisan would be able to envision the detailed structure of the recited polynucleotides. Applicants respectfully traverse these assertions.

Applicants first note that the rejection of Claims 2-3 has been obviated by cancellation of these claims. With regard to Claim 1, Applicants contend that as amended, Claim 1 meets the written description requirement. Applicants note that the Office Action has stated that claims to the nucleotide sequence of SEQ ID NO: 1, and a nucleic acid molecule which encodes the polypeptide of SEQ ID NO: 2 or 3, meets the written description requirement (page 7 of the Office Action).

With regard to subsection (c) of Claim 1, the Federal Circuit has recently recognized that claims directed to nucleic acid molecules that hybridize under highly stringent conditions to a disclosed sequence meet the written description requirement. Specifically, the Federal Circuit has noted that a claim that recites a genus of nucleotide sequences based on their hybridization properties “may be adequately described if [the claimed nucleic acid molecules] hybridize under highly stringent conditions to known sequences because such conditions dictate that all species within the genus will be structurally similar.” *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1327 (Fed. Cir. 2002). Claim 1(c) has been amended to recite specific hybridization conditions corresponding to “highly stringent” conditions, and the specification explicitly discloses the known

sequences SEQ ID NO: 1, 2, and 3. Thus, based upon the holding of *Enzo*, Applicants contend that this portion of Claim 1 meets the written description requirement.

Finally, with respect to complementary sequences, the specification discloses that such sequences are encompassed within the scope of the invention; furthermore, one of skill in the art would readily be able to envision the detailed structure of such sequences. Applicants contend, therefore, that Claim 1 is compliant with the written description requirement.

Applicants, believing that the rejection of the pending claims based on 35 U.S.C. § 112, first paragraph, for lack of written description have been overcome by amendment or traversed by argument, respectfully request that this ground of rejection be withdrawn.

(C) The Office Action further maintains a rejection of Claims 1-3 under 35 U.S.C. § 112, first paragraph, as not being enabled. Specifically, the Office Action asserts that the Applicant has not provided evidence to demonstrate that the skilled artisan would be able without undue experimentation to make and use the instant invention. Applicants respectfully traverse these assertions.

Applicants first note that the rejection of Claims 2-3 has been obviated by cancellation of these claims. With regard to Claim 1, Applicants contend that as amended, Claim 1 meets the enablement requirement. Applicants note that the Office Action mailed February 25, 2004 recognized that the nucleic acid molecule of SEQ ID NO: 1, and those encoding SEQ ID NO: 2 (and presumably SEQ ID NO: 3) are enabled by the specification. With regarding to hybridizing sequences, one of ordinary skill in the art could readily make and use such sequences in view of the teachings of the specification. Claim 1, as amended, recites hybridization conditions corresponding to “highly stringent” conditions. As noted in the specification (page 24, line 9), such conditions allow for approximately a 6% mismatch. Based on the disclosure of the specification, one of ordinary skill in the art could readily make a particular sequence and, using routine experimentation, test whether that particular sequence hybridized to SEQ ID NO: 1, or to a nucleic acid molecule encoding SEQ ID NO: 2 or SEQ ID NO: 3. Furthermore, one of skill in the art would readily be able to discern complementary sequences, by basic base pairing. Thus Applicants contend that Claim 1 is fully enabled by the specification.

Applicants, believing that the rejection of the pending claims based on 35 U.S.C. §112, first paragraph, for lack of enablement has been overcome by amendment or traversed by argument, respectfully request that this ground of rejection be withdrawn.

### CONCLUSIONS

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended and therefore respectfully request allowance.

If Examiner Seharaseyon believes it to be helpful, Examiner Seharaseyon is invited to contact the undersigned representative by telephone at (312) 913-0001.

Respectfully submitted,  
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Dated: 1-31-05

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